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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/779,784	02/18/2004	Naima Mezaache	54159US	9837
21967 7590 09/06/2007 HUNTON & WILLIAMS LLP INTELLECTUAL PROPERTY DEPARTMENT 1900 K STREET, N.W. SUITE 1200 WASHINGTON, DC 20006-1109			EXAMINER MONSHIPOURI, MARYAM	
			ART UNIT 1656	PAPER NUMBER
			MAIL DATE 09/06/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/779,784	Applicant(s) MEZAACHE ET AL.	
	Examiner Maryam Monshipouri	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-43 and 48-322 is/are pending in the application.
 4a) Of the above claim(s) 48-124, 130-139, 146-200 and 213-322 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-43, 125-129, 140-145 and 201-212 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>filed 12/04</u> . | 6) <input type="checkbox"/> Other: ____ |

Applicant's response to restriction requirement filed 6/20/2007 is acknowledged. Applicant elected **Group I** (claims 1-43, 125-129 and newly added claims 140-145 and 201-212) invention with traverse **and the following species**: Samaritan, glycerol palmitosearate, macrogol fatty acid esters and fast dispersing direct compression non-cushioning matrix tablet without traverse. Claims 48-124, 130-139, 146-200, 213-322 (and all non-elected species) are hereby withdrawn as drawn to non-elected invention. Claims 44-47 are canceled.

In traversal of restriction requirement applicant argues the following: that Groups III-V should be rejoined because the required searches for all groups should be substantially coextensive as they are directed to the same subject matter.

This argument was fully considered but was found **unpersuasive** due to the fact that even though, as applicant mentioned, there may be some overlap between the subject matter of Groups I and III-IV the required searches for each invention are **not coextensive** because each invention is unrelated to the other in terms of at least one of the following: formulation, ingredients and solubility profile. Therefore, applicant can appreciate that rejoinder of all said inventions does impose an undue burden of searching on the examiner. Therefore, in view of the response above, in addition to explanations provided previously restriction is hereby maintained and is hereby made **Final**.

DETAILED ACTION

Art Unit: 1656

Claims 1-43, 125-129, 140-145 and 201-212 (drawn to Sumatriptan, glycerol palmitosearate, macrogol fatty acid esters and fast dispersing direct compression non-cushioning matrix tablet) are under examination on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-43, 125-129, 14-145, 201-212 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "5-Ht agonist" in claim 1 (and its dependent claims 1-4, 10-30, 127-129, 140, 142, 201-212) is unclear. Applicant has not defined said phrase explicitly in the specification. Therefore, the metes and bounds of said phrase is indefinite.

Claims 1-43, 125-129, 14-145, 201-212 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrases "shperonization aid" and solubility enhancer" in claim 1 (and its dependent claims 1-30, 125-129, 140, 201, 203, 205, 207) is indefinite. Again, said phrases have not been explicitly defined in the disclosure. Therefore, the metes and bounds of said phrases are indefinite.

Claim 28, which depends from claim 27 recites the limitation "taste masking coating". There is insufficient antecedent basis for this limitation in the claim.

Claims 30 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unknown what "Povidine K30 " is.

Claims 23-25, 26, 35, 37 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unknown what is the structure of "Gelucire 50/13" and "Gelucire 44/14" in claim 23 (and its dependent claims 24-26, 35, 37). Appropriate clarification is required.

Claims 201-202, 205-206, 209-210 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "Intense Peppermint" in each of said claims is unclear. It is unknown what structure constitutes said phrase.

Claims 207-208, 211-212 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear as to what "Magnasweet 100" , recited in each mentioned claim is. There is no definition provided for said phrase in the disclosure. Appropriate clarification is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

Art Unit: 1656

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-43, 125-129, 140-145 and 201-212 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ahlgren et al. (U.S. Patent No. 6,117,452, issued 9/12/2000) in view of current drug formulation/preparation techniques. Ahlgren teaches a fast dissolving (see release times in Examples III-IV) comestible composition (which is a pharmaceutical composition by inherency) optionally in the form of tablets comprising a combination of fatty acid esters including glycerol palmitostearate which can also comprise of surfactants/emulsifiers etc. and an active agent. In column 4, Ahlgren teaches Sumatriptan (a 5-HT agonist for treating migraine) as an active ingredient which may be used in its composition. Gelucire 50/13, which is a macrogol fatty acid ester by inherency was utilized in most of microsphere preparations of Ahlgren (see for example, table contents of columns 8-9). In column 8 Ahlgren teaches about coating microspheres with ethylcellulose mixtures (which inherently include negatively and positively charged derivatives of said ethylcellulose). In column 6 lines 33-39, Ahlgren teaches that sweeteners, flavourants etc. may be used in its compositions. Ahlgren does not explicitly teach a rapid absorption composition with Sumatriptan, glycerol palmitoestearate and "Gelucir 50/13", optionally with "ethylcellulose E45" and "Povidone K30", at ratio's such as those recited in claim 36, optionally, comprising specific sweeteners and/or flavorants of this invention.

Current drug formulation techniques teach that once a useful product (drug) such as sumatriptan is identified it is routine to add spheronization agents, solubility

Art Unit: 1656

enhancers, coating materials, sweeteners to said products and optimize their ratio's depending on the particular route of drug administration and the release profile required.

At the time the invention was made it would have been obvious to one of ordinary skill in the art to start with the composition of Ahlgren and replace the active ingredients thereof with Sumatriptan and then add spherization agents, solubility enhancers, coating materials, sweeteners to said products (including those provided in this invention) and optimize their ratio's such that the fastest acting best tasting oral compositions are obtained, according to current drug formulation techniques. Such compositions inherently will be ingestible without water.

One of ordinary skill in the art is motivated in optimizing such Sumatriptan composition because it is highly desirable for migraine patients to be dispensed with Sumatriptan compositions which can be dispensed immediately (such as tablets) even in the absence of drinking water, which also act as quickly as possible at the onset of migraine headache, rendering the invention obvious.

Finally, one of ordinary skill in the art has a reasonable expectation of success in formulating such compositions because such drug release optimization methods depending on the route of administration are merely routine in the prior art.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maryam Monshipouri whose telephone number is (571) 272-0932. The examiner can normally be reached on Tues.-Fri., from 7:00 a.m to 5:30 p.m..

Art Unit: 1656

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleene Kerr Bragdon can be reached on (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

re. Monship

Maryam Monshipouri Ph.D.

Primary Examiner
